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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/529,442	04/13/00	LAAKSO	T. 003300-634

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EXAMINER

DEWITTY, R

ART UNIT

PAPER NUMBER

1616

DATE MAILED:

07/23/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/529,442

Applicant(s)

LAAKSO ET AL.

Examiner

Robert M DeWitty

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 April 2000.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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DETAILED ACTION

Claims 1-22 are pending in the instant application.

Acknowledgement is made of Applicant's amendment filed 4/13/00.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. Claims 1-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, Applicant has stated limitations and alternative limitations in several of the claims. One with ordinary skill in the art would not be able to determine the meets and bounds set forth in the claims. For example, in claim 1, lines 9 and 16, an alternative method is given; in claim 4, line 34, an alternative method is given, in claim 4, line 36, "and/or" for a limitation is given; in claim 5, lines 3 and 4, "and/or" for a limitation is taught; in claim 7, lines 10,11, the polymer can be "insoluble or slightly insoluble"; claim 9, line 21, "and/or" for a limitation is given; claim 11, line 37, "and/or" is taught for a limitation. Appropriate correction is required for the claims.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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2. Claims 1-22 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Specifically, one with ordinary skill in the art does not know when to choose "b1" or "b2" as taught by claim 1.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tice et al. in view of Ekman et al.

Tice et al. (U.S. Pat. No. 5,407,609) relates to a method of microencapsulating an agent to form a microencapsulated product. To prepare microcapsules or microspheres by the invention as taught by Tice et al., a polymer is first dissolved in a solvent. The solvent used can be selected from a variety of common organic solvents (col. 3, lines 49-65). Biodegradable polymers can be used as the polymer, such as poly(lactide-co-glycolide) (col. 4, lines 3-29). The active substance is then added to the solvent containing the polymer. Suitable active substances are quite extensive, as shown in Tice et al. at col. 4, line 32-col. 5, line 49.

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The solvent mixture dispersion is added to a continuous process medium to form microdroplets. Regarding the continuous process medium, Tice et al. expressly teaches that when water is used to dissolve the excipient (active substance), organic solvents and oils can be used as the process medium (col. 5, lines 50-56). The process medium is then transferred to an extraction medium, following which the microdroplets are collected (col. 6, lines 23-45).

However, Tice et al. does not teach the use of polyethylene glycol as the continuous process medium.

Ekman et al. (U.S. Pat. No. 4,822,535) relates to the production of small spherical polymer particles. Ekman et al. teaches that when using an organic solvent as a phase when producing droplets, organic solvent is not very desirable from the standpoint of environmental care and potential damage to the encapsulated particles (col. 1, lines 37-48). In several embodiments of the invention, Ekman et al. teaches a dissolved substance in a phase to be dispersed in the form of small droplets, and the droplets are solidified by removing water therefrom. One way to achieve the removal of water from the dispersed phase comprises the addition of substances, for example polyethylene glycol to be used as the polymer in the continuous phase (col. 3, lines 15-25).

In another embodiment, the polymer solution is dehydrated during the phase separation and the dispersed phase is precipitated as solid particles. The polymer used in the continuous phase is primarily polyethylene glycol (col. 4, lines 1-34).

In yet another embodiment, a polymer whose solubility in water is highly dependent on temperature is used as a dissolved substance, and conversion of the droplets to solid form is effected by cooling the system. In this embodiment, the polymer may be any polymer capable of forming a two phase system, however when the polymer in the dispersed phase is starch, the polymer in the continuous phase is polyethylene glycol (col. 4, lines 46-68).

In both the fourth, fifth, and sixth embodiments, the polymer in the continuous phase is preferably polyethylene glycol.

Based on the art available at the time the invention was made, the method of encapsulating an active substance whereby a biodegradable polymer is dissolved in an organic solvent, an active substance is dissolved in water or an organic solvent, and the two dispersions are mixed and added to polyethylene glycol as a continuous phase would have been known to one of ordinary skill in the art. Motivation to utilize polyethylene glycol as the continuous phase is taught by Ekman et al. There are less side effects as opposed to using standard organic solvents when making microparticles as, for example, those of Tice et al.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert M. DeWitty whose telephone number is 703-308-2411. The examiner can normally be reached on 9:00am - 5:00pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jose Dees can be reached on 703-308-4527. The fax phone number for the organization where this application or proceeding is assigned is 703-308-7924.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

RMD
July 19, 2001

A handwritten signature in black ink, appearing to read "Neil S. Levy". The signature is fluid and cursive, with the first name "Neil" and last name "Levy" clearly distinguishable.

NEIL S. LEVY
PRIMARY EXAMINER